

amended to insert the seed deposit information upon an indication that the claims are otherwise allowable.

**C. Claim Objection**

The Action objects to claim 8 based on an informality. In response, it is noted that the claim has been amended. The amendment does not narrow the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. The objection should now be moot.

**D. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph**

The Action rejects claims 1-32 under 35 U.S.C. §112, second paragraph in sixteen separate rejections as allegedly being indefinite for failing to particularly point out the subject matter which Applicants regard as the invention. Applicants responses to the rejections are set forth below in the order they appear in the Action:

(1) Rejection of claims 1-32:

Applicants note that the rejected claims will each be amended upon the allowance of the case to recite the accession number for a deposit of seeds of the inbred corn plant LH246. Removal of the rejection is thus respectfully requested.

(2) Rejection of claim 6:

Applicants note that claim 6 has been amended to specify that the plant is “further defined as comprising a gene conferring male sterility.” The amendment does not narrow the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. It is believed that the rejection is now moot in light of the amendment.

(3) Rejection of claim 8:

Applicants note that the claim has been amended to replace “being from” with “having been isolated from.” The amendment does not narrow the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. It is believed that the rejection is now moot in light of the amendment.

(4) Rejection of claim 9:

Applicants note that the claim has been amended to replace “is capable of expressing” with “expresses.” It is believed that the rejection is now moot in light of the amendment.

(5) Rejection of claim 10:

Applicants note that the claim has been amended by replacing “such a” with “said.” The amendment does not narrow the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. It is believed that the rejection is now moot in light of the amendment.

(6) Rejection of claim 17:

Applicants note that the claim has been amended by inserting “seed” after “inbred LH246.” The amendment does not narrow the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. It is believed that the rejection is now moot in light of the amendment.

(7) Rejection of claim 18:

Applicants note that the claim has been amended to insert “further” after “step (c).” The amendment does not narrow the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. It is believed that the rejection is now moot in light of the amendment.

(8) Rejection of claims 19-25:

Applicants respectfully traverse the rejection. With respect to claims 20, 22-23 and 25, it is noted that the claims have been canceled and thus the rejection is moot. With respect to the remaining claims, it is noted that the term "LH246-derived" is fully definite as it is used in the claims. The term "derived" has a well-known meaning in the art and the term is defined in the relevant claims based on the steps given in the claim. In particular, claim 19 is directed to a method of "producing a LH246-derived corn plant." Recited in the claim are the steps for producing the LH246-derived corn plant. Claim terms must be read in view of the claim language as a whole. The meaning of the term is thus clear in view of the steps given. Accordingly, "LH246-derived" has a definite meaning to one of skill in the art. Removal of the rejection is thus respectfully requested.

(9) Rejection of claims 20, 23, 25 and 29:

Applicants respectfully traverse the rejection but note that, in the interest of compact prosecution of the case, the subject claims have been cancelled without prejudice or disclaimer. The rejection is thus now moot.

(10) Rejection of claim 24:

Applicants respectfully traverse the rejection. The claim is fully definite based on the positive steps that are set forth in the claim, namely the use of plant tissue culture methods to derive progeny. As the claim refers to deriving progeny of "said LH246-derived corn plant," which is the result of the last step in claim 19, there is no indefiniteness as to when the tissue culture methods are used. The methods could only be used after step (b) is completed, since it is only after this step that there is a "LH246-derived corn plant" in accordance with claim 19. "Utilizing" plant tissue culture is further not indefinite because the claim recites the positive step

of utilizing plant tissue culture methods *to derive progeny*. This is not narrative. Utilizing plant tissue culture methods to derive progeny denotes a positive action and the limitation to plant tissue culture methods fully defines what this positive action is. The cited claim term must be viewed in light of the claim as a whole, including the claim from which it depends and all the limitations recited within the claim. When this is done, it is readily apparent that the metes and bounds of the claim are fully defined in compliance with the second paragraph of 35 U.S.C. § 112. Removal of the rejection is thus respectfully requested

(11) Rejection of claim 25:

Applicants respectfully traverse the rejection but note that, in the interest of compact prosecution of the case, the subject claim has been cancelled without prejudice or disclaimer. The rejection is thus now moot.

(12) Rejection of claim 27:

In response, Applicants note that claim has been amended to specify that progeny are produced as a result of the crossing. In view of the amendment, it is believed that the rejection is now moot.

(13) Rejection of claim 28:

As set forth immediately above, the rejection is moot in light of the amendment to claim 27.

(14) Rejection of claim 30:

Applicants respectfully traverse the rejection. It is first noted that the term “which include” has been replaced with “comprising.” It is believed that the amendment renders the rejection moot. However, to the extent that the rejection is made with regard to the remaining claim language, it is noted that the claim sets forth positive steps in full compliance with the

second paragraph of 35 U.S.C. § 112. As amended, claim 30 specifies a method for developing a corn plant in a corn plant breeding program using plant breeding techniques comprising employing the corn plant of claim 2, or its parts, as a source of plant breeding material. The claim thus recites the positive step of using the corn plant of claim 2, or its parts, as a source of breeding material in a corn plant breeding program using plant breeding techniques. Use of a plant as a source of breeding material in a corn plant breeding program is a well known process in the art that forms the basis of how new corn inbreds are made. This is set forth at pages 2-4 of the specification. One of skill in the art would thus more than readily understand and recognize this positive step. The second paragraph of 35 U.S.C. § 112 merely requires that it be clear to those skilled in the art what Applicant intends to claim. What is dispositive is whether one of ordinary skill in the art would understand what is claimed when the claims are read in light of the specification. The claim cannot therefore be considered indefinite for failure to recite a positive step. Removal of the rejection is thus respectfully requested.

(15) Rejection of claim 31:

In response, Applicants note that the preamble of claim 31 has been amended to specify “The method for developing a corn plant in a corn plant breeding program of claim 30.” The amendment does not narrow the scope of the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. It is believed that the rejection is now moot in light of the amendment.

(16) Rejection of claim 32:

Applicants respectfully traverse the rejection but note that, in the interest of compact prosecution of the case, the subject claims have been cancelled without prejudice or disclaimer. The rejection is thus now moot.

In view of the foregoing, Applicants respectfully request the removal of the rejections under 35 U.S.C. §112, second paragraph.

**E. Rejection of Claims Under 35 U.S.C. §112, First Paragraph**

The Action rejects claims 1-32 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

(1) The Action rejects claims 12-16, 20-23, 25-29, 31, and 32 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Applicants respectfully traverse the rejection. With respect to claims 20, 22-23, 25-26, 28-29 and 32, it is first noted that the claims have been canceled without prejudice or disclaimer and thus the rejection of these claims is now moot. With respect to the remaining claims, the claimed subject matter has been described in full compliance with the first paragraph of 35 U.S.C. §112, first paragraph. In particular, the specification provides a description of sufficient structural characteristics of hybrid plants having inbred corn plant LH246 as one parent to satisfy the written description requirement. For example, the specification describes, in Tables 1-4, four hybrids that were produced using LH246 as one parent. Described in the tables are the mean yield, percentage moisture, stalk lodging, root lodging, percent of dropped ears, plant height and ear height for these hybrids. This information, combined with the descriptions of the genetic and morphological characteristics of LH246 in the specification, is more than adequate to provide a description of hybrid plants and seeds derived from corn plant LH246 in compliance with the written description requirement. While the claims are directed to a genus of plants, these four hybrids constitute a

representative set of species describing the genus based on the shared structural characteristics of the members of the genus.

Because corn plant LH246 is an inbred corn plant, all hybrid plants having LH246 as a parent will contain the same genetic contribution from LH246 and thus will be genetically distinct and identifiable from any other corn plant on this basis. That is, because LH246 is an inbred corn plant, all hybrid corn plants derived therefrom must inherit exactly half of the genetic material of corn plant LH246. All hybrid plant derived from LH246 will thus be genetically identical with respect to this genetic contribution. The Federal Circuit has noted that such shared structural features possessed by members of a genus is important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where “it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*” (emphasis added)). Here, all of the members of the claimed genus of hybrids having LH246 as one parent share the identical structural feature of having the genetic complement of LH246. One of skill in the art could thus readily identify the members of the genus. The written description requirement has therefore been fully complied with.

The Action also rejects claims to corn plant LH246 which has been transformed with one or more transgenes. However, such plants are fully described by way of the description of corn plant LH246 and representative transgene species, including the accompanying phenotypic effect of the transgenes. Examples of just some of the transgenes and the associated phenotypic traits described in the specification include the following: genes that that confer resistance to herbicides

or antibiotics such as (a) a neomycin phosphotransferase II (nptII) gene, isolated from transposon Tn5, conferring resistance to kanamycin, (b) a hygromycin phosphotransferase gene conferring resistance to the antibiotic hygromycin, (c) streptomycin phosphotransferase, gentamycin acetyl transferase and aminoglycoside-3'-adenyl transferase, conferring resistance to antibiotics; screenable marker genes including, (a)  $\beta$ -glucuronidase, (b) luciferase, (c) chloramphenicol acetyltransferase, and (d) Green Fluorescent Protein (GFP); genes that confer resistance to pests or disease including (a) the tomato Cf-9 gene for resistance to *Cladosporium fulvum*, (b) the tomato Pto gene for resistance to *Pseudomonas syringae* pv., (c) an *Arabidopsis* RSP2 gene for resistance to *Pseudomonas syringae*, (d) a *Bacillus thuringiensis* insecticidal protein gene, (e) a vitamin-binding protein such as avidin, (f) an enzyme inhibitor, for example, a protease or proteinase inhibitor or an amylase inhibitor, and (g) an insect-specific hormone or pheromone such as an ecdysteroid and juvenile hormone; a mutant 5-enolpyruvyl-3-phosphokimate synthase (EPSP) or aroA gene conferring resistance to glyphosate; antisense stearyl-ACP desaturase to increase stearic acid content of the plant; a phytase-encoding gene enhancing breakdown of phytate, adding more free phosphate to the transformed plant; and a gene coding for an enzyme that alters the branching pattern of starch such as an  $\alpha$ -amylase or tomato invertase gene.

The foregoing examples constitute a representative set of species supporting a description of the genus of transformed LH246 plants. To conclude otherwise would limit Applicants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations



omitted)). While Applicants have not described every possible single species of transgenes introduced into LH246, this is not required to provide a written description of a genus. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). As such, Applicants have fully complied with the written description and removal of the rejection under 35 U.S.C. §112, first paragraph, is thus respectfully requested.

(2) The Action rejects claims 1-32 under 35 U.S.C. §112, first paragraph, based on the need for a deposit of seed of corn variety LH246.

In response, Applicant notes that a deposit of 2,500 seeds of the inbred LH246 will be made with the ATCC upon the allowance of the case. The deposit will be made in accordance with the terms and provisions of 37 C.F.R. §1.808 relating to deposits of microorganisms. The deposit will be made for a term of at least thirty years or at least five years after the most recent request for furnishing of a sample of the deposit is received by the depository or for the effective life of the patent, whichever is longer. A declaration certifying that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809 will be provided and the claims will be amended to recite the accession number for the deposit.

In light of the foregoing, Applicant respectfully requests that the rejection of claims 1-32 under 35 U.S.C. §112, first and second paragraphs, be withdrawn.

(3) The Action rejects claims 26-28 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. In particular, the Action alleges that the specification does not adequately describe the corn variety LH246 comprising a transgene. Applicants respectfully traverse.

In response, it is first noted that all that is required to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph, is that Applicants teach one reasonably skilled in the art how to make and use the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The specification has done this and thus fully meets the requirement.

Claim 26 is directed to corn plant LH246 or parts thereof “wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.” The Action appears to reject this and the other claims as allegedly failing to “adequately describe the corn plant having been transformed so that its genetic material contains one or more transgenes.” However, this allegation is not understood. As set forth above, Applicants must only teach one of skill in the art to make and use the invention. Applicants have more than adequately done so. For example, the specification provides corn line LH246, which will be deposited upon the indication of otherwise allowable subject matter. The specification also describes numerous plant transformation techniques that are known in the art at pages at pages 29-31, including: *Agrobacterium*-mediated transformation; microprojectile-mediated transformation; sonication of target cells; liposome or spheroplast fusion; electroporation of protoplasts and whole cells and tissues; and direct uptake of DNA into protoplasts using  $\text{CaCl}_2$  precipitation, polyvinyl alcohol or poly-L-ornithine.

The specification further describes numerous coding and regulatory sequences for transformation into corn plant LH246 using the transformation techniques described including numerous examples of plant disease resistance genes, *Bacillus thuringiensis* protein genes, genes that confer resistance to a herbicide; genes that confer or contribute to a value-added trait, inducible promoters, constitutive promoters, tissue-specific promoters, and signal sequences for

targeting proteins to subcellular compartments. This teaching is more than adequate to teach one of skill in the art to introduce one or more transgenes into corn variety LH246.

It is finally noted that the Action provides no basis for doubting the sufficiency of the teaching in Applicants' specification and thus the enablement of Applicants' claims. A mere allegation that Applicants have not met the enablement requirement of 35 U.S.C. §112, first paragraph, will not support a rejection, "[o]therwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *In re Marzocchi*, 169 U.S.P.Q. at 370. Absent such a basis, the rejection must fail.

In view of the foregoing Applicants respectfully request the removal of the rejection

**E. Rejection of Claims Under 35 U.S.C. §102(b)/103(a)**

The Action has rejected claims 12-16, 20, 22, 23, 25, 29 and 32 under 35 U.S.C. §102(b)/103(a) as allegedly anticipated or, in the alternative, obvious over Eggerling (U.S. Patent 5,276,266). Applicant respectfully traverses.

The rejection is made based on the allegation that "depending upon what second corn plant one of skill in the art selected, the resulting corn seed and progeny *could be* genetically, morphologically and physiological indistinguishable from that of the instant claims." Emphasis added. However, what *could* happen is irrelevant. Under 35 U.S.C. § 102(b) it is the burden of the Office to show that each and every element as set forth in the claim is found in the prior art. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). This has not been done and the rejection must therefore fail.

To the extent that alleged unexpressed inherent characteristics form the basis of an anticipation rejection, it is noted by Applicants that these characteristics must necessarily flow from the disclosure. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."). Here, all that is stated in the Action is that, under a hypothetical set of circumstances, the claims allegedly could be anticipated. However, the Action not only does not indicate that these circumstances ever *have* occurred prior to the filing of the application, there is not even a showing that such circumstances *could* occur, *e.g.*, that a set of corn plants exist in the prior art that could be crossed to arrive at the claimed invention. The Action has thus clearly failed to meet the burden under 35 U.S.C. §102(b).

Similarly, in order to establish a *prima facie* case of obviousness under 35 U.S.C. §103, three criteria must be met: (1) there must be some motivation or suggestion in the cited prior art or in the knowledge generally available to one of skill in the art to combine the teachings to arrive at the invention, (2) there must be a reasonable expectation of success, and (3) the prior art must teach or suggest all claim limitations. *See In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991), *see also*, M.P.E.P. § 2142. All three of these criteria are missing in the instant rejection. First, there is no motivation or suggestion in the prior art to arrive at the invention and no rationale for such a motivation has been alleged in the Action. The rejection thus relies on an "obvious to try" type rationale. This approach has been rejected by the Federal Circuit. *See In re O'Farrell*, 853 F.2d 894, 903. Second, one of skill in the art would have no reasonable

expectation of success in selecting a second inbred corn plant to arrive at the invention. For example, there is no indication or showing in the Action that a second corn plant that could be used to produce progeny within the scope of the claims even exists, let alone the motivation for one of skill in the art to cross this plant with LH246. Finally, the Action has not shown that the prior art teaches or suggests all of the claim limitations. Without such a teaching of all of the claim limitations, one of skill in the art would lack the guidance necessary to arrive at the invention.

In view of the foregoing Applicant respectfully requests removal of the rejection.

**F. Conclusion**

This is submitted to be a complete response to the referenced Office Action. In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned at (512)536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Robert E. Hanson  
Reg. No. 42,628  
Attorney for Applicant

FULBRIGHT & JAWORSKI, L.L.P.  
600 Congress Ave., Ste. 1900  
Austin, Texas 78701  
(512) 474-5201

Date: September 11, 2002

## APPENDIX A: VERSION OF AMENDMENTS MARKED TO SHOW CHANGES

Please cancel claims 20, 22-23, 25, 29 and 32 without prejudice or disclaimer.

Please amend claims 6, 8-10, 17-18, 27 and 30-31 as follows:

6. (Amended) The corn plant of claim 2, wherein said plant is further defined as comprising a gene conferring male sterility[e].
8. (Amended) [A] The tissue culture according to claim 7, the cells or protoplasts of the tissue culture [being from] having been isolated from a tissue selected from the group consisting of leaves, pollen, embryos, roots, root tips, anthers, silks, flowers, kernels, ears, cobs, husks, and stalks.
9. (Amended) A corn plant regenerated from the tissue culture of claim 7, wherein the regenerated plant [is capable of expressing] expresses all the morphological and physiological characteristics of inbred line LH246.
10. (Amended) A corn plant with all of the physiological and morphological characteristics of corn inbred LH246, wherein said corn plant is produced by a tissue culture process using the corn plant of claim 5 as the starting material for [such a] said process.
17. (Amended) A method for producing inbred LH246 seed, representative seed of which have been deposited under ATCC Accession No. \_\_\_\_\_, comprising:
  - a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred LH246, said collection also comprising seed of said inbred;
  - b) growing plants from said collection of seed;
  - c) identifying inbred parent plants;
  - d) controlling pollination in a manner which preserves the homozygosity of said inbred parent plant; and
  - e) harvesting the resultant seed.
18. (Amended) The process of claim 17 wherein step (c) further comprises identifying plants with decreased vigor.

20. (Canceled) A LH246-derived corn plant, or parts thereof, produced by the method of claim 19, said LH246-derived corn plant expressing a combination of at least two LH246 traits selected from the group consisting of: a relative maturity of approximately 72 to 82 days, high yield, above average stalk strength, above average test weight, above average stay green, good stalk lodging resistance, and adapted to the Central Corn Belt, Northeast, Northcentral, Southeast, Southcentral, Southwest or Western regions of the United States.
22. (Canceled) A further LH246-derived corn plant, or parts thereof, produced by the method of claim 21.
23. (Canceled) The further LH246-derived corn plant, or parts thereof, of claim 22, wherein said further LH246-derived corn plant, or parts thereof, express a combination of at least two LH246 traits selected from the group consisting of: a relative maturity of approximately 72 to 82 days, high yield, above average stalk strength, above average test weight, above average stay green, good stalk lodging resistance, and adapted to the Central Corn Belt, Northeast, Northcentral, Southeast, Southcentral, Southwest or Western regions of the United States.
25. (Canceled) A LH246-derived corn plant, or parts thereof, produced by the method of claim 24, said LH246-derived corn plant expressing a combination of at least two LH246 traits selected from the group consisting of: a relative maturity of approximately 72 to 82 days, high yield, above average stalk strength, above average test weight, above average stay green, good stalk lodging resistance, and adapted to the Central Corn Belt, Northeast, Northcentral, Southeast, Southcentral, Southwest or Western regions of the United States.
27. (Amended) A method for producing a corn plant that contains in its genetic material one or more transgenes, comprising crossing the corn plant of claim 26 with either a second plant of another corn line, or a non-transformed corn plant of the line LH246, wherein progeny are produced, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element.

29. (Canceled) A corn plant, or parts thereof, wherein at least one ancestor of said corn plant is the corn plant of claim 2, said corn plant expressing a combination of at least two LH246 traits selected from the group consisting of: a relative maturity of approximately 72 to 82 days, high yield, above average stalk strength, above average test weight, above average stay green, good stalk lodging resistance, and adapted to the Central Corn Belt, Northeast, Northcentral, Southeast, Southcentral, Southwest or Western regions of the United States.
30. (Amended) A method for developing a corn plant in a corn plant breeding program using plant breeding techniques [which include] comprising employing a corn plant, or its parts, as a source of plant breeding material comprising: using the corn plant, or its parts, of claim 2 as a source of said breeding material.
31. (Amended) The method for developing a corn plant in a corn plant breeding program of claim 30 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.
32. (Canceled) A corn plant, or parts thereof, produced by the method of claim 30.